STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	150125	A. BUILDING 00 B. WING	04/19/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PERCEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
S0000	This visit was for a State hospital licensure survey. Dates: 4/16/12 through 4/19/12 Facility Number: 005106 Surveyors: Albert Daeger, CFM, SFPIO Medical Surveyor Saundra Nolfi, RN PH Nurse Surveyor QA: claughlin 05/03/12	S0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determined that other safegaurds provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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S0406	410 IAC 15-1.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-1.4-2(a)(1) (a) The hospital shall have an effective, organized, hospital-wide, comprehensive quality assessment and improvement program in which all areas of the hospital participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following: (1) All services, including services furnished by a contractor. Based on document review, the facility failed to ensure 1 service provided by a contractor as part of its comprehensive quality assessment and improvement (QA&I) program. Findings included: 1. Staff member #3 provided the contracted services that are reviewed by the Quality Assurance committee. The Contracted Services for Direct Patient Care does not include laundry/linen as one of the services that was evaluated. 2. At 9:00 AM on 4/18/2012, staff member #3 indicated laundry/linen contracted service has never been evaluated by Community Hospital Quality Assessment committee.	S0406	April 20, 2012 the contracted linen services quality report was officially added to the Hospital Quality Reporting System. The report will be given to Hospital Quality Committee on a quarterly basis. Any fallout will be reviewed and a corrective action plan will be instituted and monitored. The outside service will be responsible for implementing the correction needed on their end. The outside service will provide the action plan taken to correct the deficiency. The report of the correction actions will be submitted to the Hospital Quality Committee until such time that a consistent, positive corrective action is documented. The Chairperson of Hospital Quality and the Director of Environmental Services will have direct responsibility for the data evaluation and any corrective	04/20/2012

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			action needed.	

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S0606	410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(f)(3)(D)(viii) (f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows: (3) The infection control committee responsibilities shall include, but not be limited to, the following: (D) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following: (viii) An employee health program to determine the communicable disease history of new personnel as required by state and federal agencies. Based on document review and staff interview, the hospital failed to monitor the immune status of 6 of 17 health care workers related to Rubella, Rubeola and Varicella (#3, 4, 6, 7, 8 and 10). Findings: 1. Six of 17 health care workers personnel files were reviewed for reliable documentation of immunization to Rubella, Rubeola and Varicella: #3, 4, 6, 7, 8, and 10. The health section of their files did not have reliable documentation the 6 staff members were immune to Rubella, Rubeola and Varicella. 2. CDC recommends for Healthcare personnel (HCP) born in 1957 or later without serologic evidence of Rubella and	S0606	EHS 102 - Policy Health Screen and Health Interview - New EmployeesPolicy updated to include: As of 5/01/2012 all new hires working in the healthcare setting should be immune to rubeola, mumps, rubella and varicella. This includes employess under OSHA catagories I thru III. Proof of immunity will be indicated by one of the following:1. Laboratory confirmation2. Physician documenatation of disease3 Documentation of 2 doses of live measles and mumps vaccine given on or after the first birthday, separated by 28 days or more. At least one dose of live rubella vaccine. Documentation of 2 doses of varicella vaccine given	05/01/2012

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	Rubeola immunity or prior vaccination, give 2 doses of MMR, 4 weeks apart and HCP who have no serologic proof of Varicella immunity, prior vaccination, or history of varicella disease, or give 2 doses of varicella vaccine, 4 weeks apart. 3. Community Hospital Health Screen and Health Interview policy/procedure number EHS-102 section 3.6.3 states, "All new employees classified as OSHA I and II should be immune to rubeola, mumps, rubella, and varicella. Employees that are OSHA class III that have no evidence of immunity will be titered in the event of an exposure. If their titer is negative to the exposed disease they will be restricted from work in accordance with Infection Prevention policy on Employee Work Restrictions." 4. Community Hospital OSHA Categories policy/procedure number IF 6.1 states, "The management personnel must enforce existing occupational safety and health standards (OSHA). The Community Hospital isolation system is Standard Precautions including Airborne Precautions, Contact Precautions and Droplet Precautions. All work tasks with the hospital are classified according to one of three categories: Category I - Tasks that involve exposure to blood, body fluid, or tissue; Category II - Tasks that involve no exposure to such substances, but may require unplanned Category I		at least 28 days apart. Employees hired prior to 5/1/12 that have no evidence of immunity will be titered in the event of an exposure. If their titer is negative to the exposed disease they will be restricted from work in accordance with Infection Prevention policy on Employee Work Restrictions.Employee Health will monitor all appropriate employees to meet compliance with policy. The Employee Health personnel are under the direction of the Director of Human Resources, who has overall responsibility.5/31/2012 - MODIFICATION:Policy IF 7.4 Employee Work Restrictions - In the event of a community outbreak of disease, ie rubeola,mumps, rubella o r varicella, employees that have no evidence of immunity or vaccination will be titered. Refer to Table 1 within this policy for work restriction and durarion of restrictions guidelines.	

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	tasks; and Category III - Tasks that involve no exposure to such substances." 5. At 11:00 AM on 4/18/2012, staff member #37 indicated a policy was written since their previous licensure survey in 2010. The staff member indicated the policy refers to OSHA categories I to III which category III staff personnel do not need to have documentation confirming they were immune to Rubella, Rubeola and Varicella. Staff member #37 confirmed staff member's #3, 4, 6, 7, 8, and 10 fall under category III. 6. At 9:22 PM on 4/19/2012, OSHA Compliance Officer responded to Community Hospital policies regarding OSHA categories I to III on exposure risks to health care workers. The OSHA Compliance Officer indicated the OSHA Categories in the hospital policy was generated from them and their policy does not reference the OSHA General Industry Standards at all. The policy speaks to a pre-employment physical based on task to be performed. 29 CFR 1910.134 speaks to a respiratory physical being required only if the employee was required to wear a NIOSH approved respirator as a part of their employment. All employees that work in a hospital in any capacity does have a higher risk to exposure due to the place of their employment. The Compliance officer continued, in short,			

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	29 CFR 1910.1030 would apply to all employees regardless of position. The standard speaks in specifics to different areas in a hospital that already have an increased risk. Policy 6.1 states Category III employees have no exposure to substances, but it does not mean they are not at risk of exposure.			

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S0610	410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(f)(3)(D)(x) (f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows: (3) The infection control committee responsibilities shall include, but not be limited to, the following: (D) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following: (x) A program of food preparation and storage for all personnel involved in food handling which includes, but is not limited to, the following: (AA) Storage of employee food in patient refrigerators. (BB) Medications in nutrition refrigerators. (CC) Refrigerator and freezer temperature monitoring. Based on observation, document review and interview, the infection control committee failed to assure Tube Feeding formula was stored in a manner that protects the items from artificial lighting and failed to ensure the patient refrigerators on the nursing units had documentation of temperature monitoring.	S0610	5/2012 - Policy –FN 6.4 Enteral /Feedings: Storage, Distribution and Preparation has been updated: 1.Enteral formulas are stored in the manufacturer's original cases. Once a case is opened, the integrity of the flap of the case is maintained to be reclosed after feeding bottle is removed. 2.Once a bottle is removed from the original container, it is	04/23/2012

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	Findings included: 1. At 1:00 PM on 4/16/2012, the Dietary Department was toured. The dry storage room was observed storing 39 cut-open cases of assorted "Enternal Nutrition" formula. The 39 cases of formula included \Jevity, Glucerna, Osmolite, Nepro, and Pulmocare. The open cases also had loose formula stacked on top of the cases. The formula was exposed to the fluorescent lights in the dry storage room. 2. At 10:15 AM on 4/17/2012, the ICU nourishment counter was storing 2 units of Osmolite and 1 unit of Nepro. The three units were not stored in a cabinet or an amber container. 3. At 10:25 AM on 4/17/2012, the 6 West Surgical Unit nourishment counter was observed storing 1 unit of Osmolite and 1 unit of Jevity not in a cabinet or an amber container. 4. The manufacturer's label for Glucerna states, "Contains light-sensitive nutrients." 5. A memorandum dated 4/17/2012 from the manufacturer of the tube feeding formulas states, "Vitamin losses occur gradually at low light exposure and faster		placed into an amber colored bag for distribution and storage on patient care units. Feeding is not removed from amber colored bag until ready to be hung at patient's bedside. 3.Unused feedings may be returned to the kitchen to be restocked. Bottles are checked by a supervisor to ensure integrity and safety of the product. Bottles should still be in amber colored bag and show no signs of tampering before being returned to stock. The Food Nutrition Services has rearranged the product on the storage racks to eliminate the exposure to light. Additionally a black tarp over the cart is being used to eliminate exposure to light. 5/3/12 - Amber bags were purchased to cover the feedings and are used to distribute the products to nursing units. Team members have been educated on the process change. The Storeroom Supervisor will insure compliance. A daily monitor is used to insure compliance. The Clinical Dietary Manager will have direct over site for the data collection, and action plan compliance. The Clinical Dietary Manager will report the information to the Vice President of Clinical Ancillary Services who has overall responsibility for all department activity. 5/29/12 - Infection Control Meeting – Food Nutrition Services will present the changes in policy, corrective	

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	in bright light. For maximum protection during storage, Abbot Nutrition recommends that ready to hang bottles be stored in the corrugated shipper."		action plan and the monitoring. Food Nutrition Services will add this information to their monthly report to Infection Control. Infection Control will do monthly inspections of the storage area for Enteral feedings to monitor for compliance. 5/2012- Policy / procedure updates were included the department monthly meeting. All employees received a copy of the new policy/procedure with a detailed explanation of the changes. PATIENT REFRIGERATION – 5/2012 - Policy FN3.60 Refrigerators/Freezers In Patient Care Areas has been updated: The policy now clearly delineates the following process: The temperature of refrigerators in the inpatient areas that FNS (Food/Nutrition Services) makes deliveries to 7 days per week are monitored and recorded. Temperature recording forms are provided to FNS Delivery Personnel for temperature documentation. The completed forms are reviewed by the respective FNS Shift Supervisor for compliance. The Personal food items (patient or staff) are not stored in the patient refrigerator. The Director of Food and Nutrition Services will have overall responsibility for compliance. The Director will review all documents will report the information to the Vice President of Clinical Ancillary Services who has overall	

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			responsibility for all department activity. 5/29/12 - Infection Control Meeting – Food Nutrition Services will present the changes in policy, corrective action plan and the monitoring. Food Nutrition Services will add this information to their monthly report to Infection Control. Infection Control will do monthly inspections of the refrigerator logs to monitor for compliance. 5/2012- Policy / procedure updates were included the department monthly meeting. All employees received a copy of the new policy/procedure with a detailed explanation of the changes.	
	6. During the tour of the facility on 04/16/12, beginning at 1:10 PM and accompanied by staff members #A1 and A2, the Emergency Department, Labor and Delivery Unit, and the Post-Partum Unit were observed to have patient refrigerators in the nourishment areas. When temperature monitoring documentation was requested, the staff members indicated the dietary staff monitored and recorded the refrigerator temperatures daily when they stocked the nourishment areas. Staff indicated the monitoring logs were kept in the dietary department and not on the units. 7. During the tour of the facility on 04/17/12, beginning at 8:50 AM and accompanied by staff members #A1 and			

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	A2, the Pediatric Unit, 3 South, IMCU-West, ICU, and the 6 West Surgical Unit were observed to have patient refrigerators in the nourishment areas. When temperature monitoring documentation was requested, the staff members indicated the dietary staff monitored and recorded the refrigerator temperatures daily when they stocked the nourishment areas. Staff indicated the monitoring logs were kept in the dietary department and not on the units. 8. The facility policy "Refrigerators/Freezers in Patient Care Areas", effective 08/10, indicated, "...1. The temperature of refrigerators/freezers in inpatient areas that FNS (Food and Nutrition Services) makes deliveries to 7 days per week are monitored and recorded on the supply delivery sheet." 9. At 10:55 AM on 04/17/12, the director, #A19, and the clinical manager, #A20, of the Food and Nutrition Department were interviewed. They indicated the dietary staff was responsible for the refrigerator temperature monitoring and previously recorded the temperatures on the restocking sheets and turned them in to their supervisors. In October of 2011, the units began faxing their "needs list" so the paper process changed. The dietary staff members			

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	indicated they were unsure of where the process broke down, but they had no documentation of any temperature monitoring since September 2011. This was not identified until the surveyor requested the monitoring logs after the tours yesterday, 04/16/12.			

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S0748	410 IAC 15-1.5-4 MEDICAL RECORD SERVICES 410 IAC 15-1.5-4 (e)(3) (e) All entries in the medical record shall be: (3) authenticated and dated promptly in accordance with subsection (c)(3). Based on policy review, medical record review, and interview, the facility failed to ensure the discharge summaries were dictated and signed according to policy in 4 of 18 closed medical records reviewed (#N2, N10, N16, and N18). Findings included: 1. The facility policy "Entries in the Medical Record", effective June 12, 2009, indicated, "...Entries of history and physicals, operative reports, consultations, and discharge summaries are authenticated by the responsible physician within twenty-four (24) days after discharge of the patient. All transcribed reports are reviewed by the author prior to authentication to verify that the document is complete, accurate and final." 2. The medical record for patient #N2, who was admitted 01/22/12 and expired 01/23/12, indicated a discharge summary dictated by the physician on 03/01/12 and	S0748	**1. Deficiency Correction:** Monitor aging of discharge summaries weekly- sending weekly notice to each dictation service to advise them of summaries to be dictated within 14 days of discharge. This then allows appropriate time for physicians to review and authenticate. (Run report at 14 days and then at 20 days)· Phone calls to physicians with discharge summaries nearing 24 days. This is also reviewed prior to the monthly No Bed List so that physicians are suspended that have DS that are not authenticated at 24 days.Offer assistance to physicians that are struggling and consistently delinquent. Find out if they need 1:1 EPIC in-basket retraining, etc.… **Prevent the deficiency from recurring in the future** · Monitor discharge summaries continually so that they do not reach delinquent status. Make phone calls to physicians and 1:1 contact. · Monthly audit of 30 closed Medical Records for timely completion of discharge summaries · Report delinquent	05/19/2012

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	signed on 03/05/12. 3. The medical record for patient #N10, who was admitted 01/10/12 and discharged 01/16/12, indicated a discharge summary dictated by the physician on 01/20/12, but not signed until 02/28/12. 4. The medical record for patient #N16, who was admitted 12/26/11 and discharged 01/17/12, indicated a discharge summary dictated by the physician on 02/19/12 and signed 02/29/12. 5. The medical record for patient #N18, who was admitted 12/30/11 and discharged 01/04/12, indicated a discharge summary dictated by the physician on 02/09/12 and signed 02/14/12. 6. At 1:30 PM on 04/18/12, staff members #A1 and A2 confirmed the medical record findings.		discharge summaries at quarterly medical record committee meeting. Also report any problem physicians and trending. 1.Who is going to be responsible for numbers 1 and 2 above? · Director Health Information Management, Supervisor Record Completion with assistance from Clinical Data Technician. The Vice President of Health Information Management has overall responsibility for the department and will review the information for compliance **1.By what date are you going to have the deficiency corrected?** **b. If the nature of the deficiency precludes completion within 30 days the Plan of Correction must be written in incremental thirty day phases. Prior to May 19, 2012** · 4/24/2012 Presented survey findings to Medical Record Committee. As a result of committee action educational letters were sent to the 4 physicians on the cases reviewed. · Monthly audit begun of 30 records /month to evaluate timeliness of discharge summaries · Phone calls made to physicians with largest volume of delinquent discharge summaries to identify issues in dictation, epic in basket, opportunities for more education. · 4/27/2012 Started weekly reporting of all delinquent	

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			discharge summaries–sending weekly emails to services **Prior to June 19, 2012** · Prepare article for June Physicians newsletter , educational materials in physician lounge · 2 nd Monthly audit of 30 records for timeliness of discharge summaries · Trending report of delinquent discharge summaries will be sent to Medical Staff President **Prior to July 19, 2012** Resolution/Correction of deficiency	

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S0754	410 IAC 15-1.5-4 MEDICAL RECORD SERVICES 410 IAC 15-1.5-4(f)(5) (f) All inpatient records, except those in subsections (g), shall document and contain, but not be limited to, the following: (5) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law. Based on policy review, medical record review, and interview, the facility failed to ensure the consent for treatment was signed according to policy for 6 of 20 inpatient closed records reviewed (#N2, N3, N7, N8, N14, and N16). Findings included: 1. The facility policy "Consent for Treatment", effective 02/15/2011, indicated, "...Upon completion of the registration process, registration will attempt to obtain an informed consent signature from the patient, by electronic signature or manual hospital consent. If signature is unable to be obtained at the completion of the registration process, admitting will follow up with the patient within 24 hours of the admission.	S0754	Policy PTR8.32.Consent for Treatment updated: to reflect if after 48 hours and no signature is obtained the Admitting staff will make a call to the next of kin to determine if a family member is available to sign for the patient. If the patient is a minor the parent that brings in the minor will sign a manual consent so relationship can be listed. 4/25/12 Staff have been re-educated on the proper way to obtain signatures. Only the patient is to sign the electronic document. If patient unable to sign and another party signs they are to sign the manual consent so the relationship can be entered. This process will be reviewed in the annual competency Registration is reviewing the electronic document to determine if relationship and witness can be added. 4/20/2012 Supervisors/Managers will be monitoring the Epic WQ for	04/25/2012

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	If signature is obtained by electronic signature, the consent will be housed at the patients encounter level in the EMR (Electronic Medical Record). If signature is obtained by a manual process, the consent will be scanned at the patients encounter level in the EMR. If responsible party of the patient must sign consent, a manual consent will be used to indicate the relationship to the patient." 2. The medical record for patient #N2, admitted 01/22/12, indicated a treatment consent signed by someone other than the patient, but lacked documentation of relationship to the patient. 3. The medical record for patient #N3, admitted 01/16/12, indicated an EMR treatment consent signature of someone other than the patient in the area designated "Patient Signature". 4. The medical record for patient #N7, an infant admitted 12/21/11, indicated an EMR treatment consent signature of someone other than the patient, and with a different last name, in the area designated "Patient Signature". 5. The medical record for patient #N8, an infant admitted 12/28/11, indicated an EMR treatment consent signature of someone other than the patient, and with a		missing documents & signatures on a daily basis. They will also do an audit of 5 accounts per day to review consents to ensure the signature was obtained correctly. Registration will complete the necessary follow-up within 24 hours of admission. As stated above they will do another follow up after 48 hours. The Patient Access Supervisor/Managers will complete this monitoring on a daily basis. Director of Patient Access has overall responsibility for the department.	

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	different last name, in the area designated "Patient Signature". 6. The medical record for patient #N14, admitted 01/16/12 through the Emergency Department and who was unable to sign, lacked a treatment consent. The patient was in the hospital until 02/13/12. 7. The medical record for patient #N16, admitted 12/26/11, indicated a treatment consent signed by someone other than the patient, but lacked documentation of relationship to the patient. The date written after the witness signature was 2/10/12, but the patient was discharged 01/17/12. 8. At 2:00 PM on 04/17/12, staff member #A59 indicated only patients were supposed to sign the EMR form and a manual, paper form was supposed to be used if someone other than the patient signed. He/she also indicated the form was supposed to be completely filled out including the relationship to the patient.			

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S0952	410 IAC 15-1.5-6 NURSING SERVICE 410 IAC 15-1.5-6(d) (d) Blood transfusions and intravenous medications shall be administered in accordance with state law and approved medical staff policies and procedures. If the blood transfusions and intravenous medications are administered by personnel other than physicians, the personnel shall have special training for these procedures in accordance with subsection (b)(6). Based on policy review, medical record review, and interview, the facility failed to ensure blood transfusions were administered according to facility policy for 4 of 5 patients who received blood transfusions (#N11, N12, N13, and N14). Findings included: 1. The facility policy "Blood Component Dispensation/Patient Care During Transfusion", effective 3/2009, indicated on page 3, "...NOTE: A second nursing personnel must also verify the identification of the patient and donor components at the bedside. Both parties must sign the Transfusion Record Form. ... 6. Pre-transfusion temperature, pulse, respiration, and blood pressure must be recorded. Vitals to be taken no more than one hour before transfusion." The policy continued on page 4, " ...9. After the first	S0952	May 2012 - Education - Annual competency has been updated to include education on "Completion of Blood Transfusion Record". This competency will occur in May 2012. Lab monitors Blood transfusion Records for incomplete/noncompliant records and an event report is entered. This is done on an ongoing basis. The non-compliance is sent to Nurse Managers for a corrective action plan. Individual staff education is done as incidents occur. Ongoing random audits will also be completed by Patient Care Services. 4/24/2012 Patient Care Services - Education on the appropriate completion of Blood transfusion Record May 2, 2012 - Standards & Practice - Education on the appropriate completion of Blood transfusion Record was reviewed May 2012 - Patient Care Unit Meetings - Education on the appropriate completion of Blood transfusion Record will be reviewed PCS	04/23/2012

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	15 minutes, the vital signs will be taken and recorded. ...11. After each unit of blood has been infused, nursing personnel must record the time, the volume and type of component administered, as well as the patient's condition and the identity of the person ending the transfusion and observing the patient. ...14. Record the post transfusion vital signs." Page 6 of the policy indicated, " Time Limitations: The blood component transfusion must be initiated within thirty minutes after removal of the blood from the Blood Bank Department OR the blood must be returned. Blood expires four hours after removal from the Blood Bank Department. ...Regardless of the amount of blood transfused, infusion must be discontinued after four hours and the bag and its contents returned to the Blood Bank Department." 2. The medical record for patient #N11 indicated a unit of blood issued from the Blood Bank at 11:00 AM on 01/08/12 and post transfusion (immediately post) vitals signs documented at 1600, 5 hours later. The form did not have any other time documented as the end time of the transfusion. The record indicated a second unit of blood was issued from the Blood Bank at 1700 on 01/08/12 and post transfusion vital signs at 2130, 4 1/2		System & Regulatory Manager and the Nurse Manager directly responsible for the staffApril 2012 - Random Audits began May 2012 - Follow up completed	

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	hours later. The second unit also lacked documentation of 2 signatures for the bedside check. 3. The medical record for patient #N12 indicated a unit of blood issued from the Blood Bank at 0245 on 12/30/11, but lacked documentation of 2 signatures of staff performing the bedside check before administering the blood. 4. The medical record for patient #N13 indicated a unit of blood issued from the Blood Bank at 1440 on 01/05/12, but had the times for the pre-transfusion vital signs and the blood start time written over/changed making it unable to determine adherence to policy. 5. The medical record for patient #N14 indicated a unit of blood issued from the Blood Bank at 1046 on 02/07/12, but had the time for the pre-transfusion vital signs written over/changed making it unable to determine adherence to policy. 6. At 1:00 PM on 04/18/12, staff members #A1 and A2 confirmed the medical record findings and indicated the time of the post transfusion vital signs was the time of the completion of the transfusion.			

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S1014	410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7(c) (c) In order to provide patient safety, the director of pharmacy shall develop and implement written policies and procedures for the appropriate selection, control, labeling, storage, use, monitoring, and quality assurance of all drugs and biologicals. Based on observation, policy review, and interview, the facility failed to ensure multidose medication vials were marked according to policy to prevent outdated use in 3 of 4 open vials observed. Findings included: 1. During the tour of IMCU-West at 9:45 AM on 04/17/12, accompanied by staff members #A1, A2, and A23, the following open multidose medication vials were observed in the cart in the med room: A. A 3 milliliter (ml) vial of Humulin R insulin, dated 07/16/13. B. A 3 ml. vial of Humulin R insulin, dated 06/11/12. C. A 10 ml. vial of Novolin N insulin, dated 06/11/12. The staff members all indicated the multidose vials should be dated when opened and discarded after 28 days.	S1014	5/12 - Policy - PHA 107.41 IV Admixture - Sterile Product Processing in Patient Care Areas has been amended to clarify the process of "Beyond Use Dates" procedure: Beyond-use dates (BUDs) for opened or needle-punctured single-dose and multiple-dose vials will comply with FDA and USP requirements. **Personnel puncturing a multiple dose vial that will be used more than a single time will write the beyond-use date and their initials on the vial.** All Patient Care Areas received the update policy and education provided by PCS System & Regulatory Manager Educational flyers were posted in all med rooms to alert staff to the appropriate labeling processInformation was included in the April "What's New , Let's Review" Educational letter. Education on the appropriate completion of Blood transfusion Record was reviewed at the Patient Care Services meeting 4/24/2012, Standards & Practice	04/24/2012

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	2. The facility policy "Administration of Medication", effective 4/11, did not address the dating of multidose vials. The facility policy "IV Admixture-Sterile Product Processing", effective 05/10, indicated on page 7, "...b. Regarding single use and multidose vials c. Beyond-use dates (BUDs) for opened or needle-punctured single use and multidose vials will comply with FDA and USP requirements. Personnel puncturing a multiple dose vial that will be used more than a single time will write the beyond-use date and their initials on the vial. Multiple-dose vial- 28 days." 3. At 9:30 AM on 04/19/12, staff member #A1 indicated the policy "IV Admixture-Sterile Product Processing" did include all multidose vials and the practice was to date the vials when opened and discard after 28 days.		meeting on 5/2/2012 and at all Patient Care Unit meetings beginning in May 2012. Random audits will be done by Pharmacy and Standards & PracticeBoth PCS System & Regulatory Manager and the Pharmacy Director are responsible for monitoring the process.	

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S1118	410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8 (b)(2) (b) The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients are assured as follows: (2) No condition shall be created or maintained which may result in a hazard to patients, public, or employees. Based on documentation review, the facility failed to ensure 2 of 2 hydrocollators are maintaining the recommended manufacturer's temperatures for Fitness Pointe Physical Therapy Department. Findings included: 1. The Hydrocollator Mobil Heating Units User Manual for the M-2 and M-4 states, "The recommended operating temperatures is 160 F to 166 F. 2. The Fitness Pointe Physical Therapy Hydrocollator Temperature Maintenance logs were reviewed for March and April 2012. The M-2 hydrocollator was tempted below 160 F 7 out of 34 days. The M-4 hydrocollator was tempted below 160 F 13 out of 34 days. The temperature logs noted there were no	S1118	4/20/2012 - Policy TS 11.15 –Cleaning the Hydrocollator Machine, Surveillance, Prevention & Control of Infection has been updated: Temperature logs are maintained. Biomed is contacted if the temperature cannot be maintained between 160-166F (manufacturer's recommendations). Procedure: 1. The minimum temperature is 160 degrees and the maximum temperature is 166 degrees.2. If the temperature is outside of the acceptable range, contact Biomed. Check the machine for proper function and safety. If the temperature is below the acceptable temperature it will be adjusted and monitored before use. If the temperature is above, then it will be tagged and not used until Biomed clears the machine for proper function and safety.A log is completed on a daily basis for both the small and large hydrocollator. Any	04/20/2012

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	corrective action taken.		discrepancies will be reported to Biomed for immediate repair.Responsible person will be supervisor of the department. The Therapy Services personnel are under the direction of the Director of Therapy Services, who has overall responsibility.The deficiency has been corrected - Policy change and log maintenance sheet were corrected as of April 20, 2012.	